1.0. 510K SUMMARY as required by: 807.92(c)

K014280 MAR 2 0 2002

2. 0 APPLICANT :

NAME **M/s. BRIGHTWAY GLOVES PVT.LTD.**

ADDRESS PIONEER MANIKANDAN BUILDINGS
VADASERY, NAGERCOIL,
TAMILNADU, INDIA-629001.

PH.NO. : 91-4652-276046, 276291

FAX NO : 91-4652-274271.

CONTACT PERSON : MR. N. PARAMASIVAN
MANAGING DIRECTOR.

3. DEVICE TRADE NAME : NIL
COMMON NAME : Patient Examination Glove (powdered)

4. Legally marketed device to which the company claiming equivalence:
Class I Patient Examination Gloves (powdered) 80LYY that meets all the requirements of ASTM D3578 .

5. **DESCRIPTION OF THE DEVICE:**

Class I Patient Examination Gloves (powdered) 80LYY that meets all 'the requirements of ASTM D3578.

6. Intended use of the Device:

Latex Examination glove (powdered) is a disposable device made of Natural Latex intended for medical purpose that is worn on the examiners hand or finger to prevent contamination between patient and examiner and is powdered with a donning powder absorbable USP corn starch.

BRIGHTWAY GLOVES PVT. LTD. NAGERCOIL

7.0 TECHNOLOGICAL CHARACTERSTICS OF THE DEVICE COMAPARED TO PREDICATE DEVICE.

Measured Parameters of Examination gloves (powdered) manufactured by Brightway Gloves			ASTM D3578 Requirement for Examination glove (powdered)
Characteristics	SIZE	Value	
1. Length	EX-S	235-240 mm	220 mm minimum
	S	235-240 mm	220 mm minimum
	M	235-240 mm	230 mm minimum
	L	235-240 mm	230mm minimum
2. Width	EX S	70MM	70 +/- 6 mm
	S	82 mm	80 +/- 6 mm
	M	93 mm	95 +/- 6 mm
	L	107 mm	111+/- 6mm
3. Thickness	EX S	0.10mm	0.08 mm minimum
	S	0.10mm	0.08 mm minimum
	M	0.10mm	0.08 mm minimum
	L	0.10mm	0.08 mm minimum

PHYSICAL PROPERTIES

	BEFORE AGEING		AFTER AGEING	
CHARACTERISTICS	BGPL VALUE *	ASTD 3578 REQUIREMENT	BGPL VALUE	ASTD 3578 Requirement
Tensile Strength	20 – 22 mpa	14 mpa min	18 – 20 mpa	14 mpa min
Elongation at break %	800 – 850%	700% min	750-800%	500% min

BGPL – BRIGHTWAY GLOVES PVT.LTD.

BRIGHTWAY GLOVES PVT. LTD. NAGERCOIL

PERFORMANCE REQUIREMENT:

Characteristics	Related defects	Level followed By		AQL followed by BGPL	AQL Value as per ASTM D3578.
		BGPL	As per ASTM D3578		
Freedom from Holes	Holes	S4	S4	1.5	4
Dimension	Width , Length Thickness.	S2	S2	4	4
Physical Property	Tensile Strength, Elongation at Break.	S2	S2	4	4

POWDER CONTENT

BGPL VALUE	ASTM REQUIREMENT
120 +/- 20 mg / glove	Max 150 mg/glove(medium size)

PROTEIN CONTENT:

BGPL VALUE	FDA REQUIREMENT
80 +/- 20 ppm	200 ppm max.

MOISTURE CONTENT:

BGPL VALUE	FDA REQUIREMENT
0.8% max	No value fixed

BIOCOMPATIBILITY:

BGPL GLOVE	FDA REQUIREMENT
Biologically Compatible	Biologically Compatible

BRIGHTWAY GLOVES PVT. LTD. NAGERCOIL

8.0 Performance Data:

The performance test data of the Latex Examination Glove (powdered) manufactured by Brightway Gloves Pvt.Ltd given below.

Measured Parameters of Examination gloves (powdered) manufactured by Brightway Gloves Pvt. Ltd.,		
Characteristics	SIZE	Value
1. Length	EX-S	235-240 mm
	S	235-240 mm
	M	235-240 mm
	L	235-240 mm
2. Width	EX S	70MM
	S	82 mm
	M	93 mm
	L	107 mm
3. Thickness	EX S	0.10mm
	S	0.10mm
	M	0.10mm
	L	0.10mm

PHYSICAL PROPERTIES

CHARACTERISTICS	Before Ageing	AfterAgeing
Tensile Strength	20 – 22 mpa	18 – 20 mpa
Elongation at break %	750 – 850%	700-800%

INSPECTION LEVEL AND AQL:

Characteristics	Related defects	Level	AQL
Freedom from Holes	Holes	S4	1.5
Dimension	Width , Length Thickness.	S2	4
Physical Property	Tensile Strength, Elongation at Break.	S2	4

BRIGHTWAY GLOVES PVT. LTD. NAGERCOIL

POWDER CONTENT: 120 +/- 20 mg per glove

PROTEIN CONTENT: 80 +/- 20 ppm

MOISTURE CONTENT: .0.8% max

BIOCOMPATIBILITY: Biologically Compatible.

9. Clinical Data : NA

10. CONCLUSION OF PERFORMANCE TEST DATA:

The Examination gloves (powdered) manufactured by M/S Brightway Gloves Pvt.Ltd,

- Meet or exceed the ASTM D3578
- Meet FDA Pin hole Requirement.
- Meet labelling claim as shown by the data in 6

11. ANY OTHER INFORMATION:

Any other information required by FDA regarding product safety and effectiveness will be provided on request.

BRIGHTWAY GLOVES PVT. LTD. NAGERCOIL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2002

Mr. N. Paramasivan
Managing Director
Brightway Gloves PVT. LTD.
Pioneer Manikandan Building
Vadasery, Nagar Coil,
Tamil Nadu,
INDIA

Re: K014280
Trade/Device Name: Latex Examination Gloves (Powdered)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: December 27, 2001
Received: December 27, 2001

Dear Mr. Paramasivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DUPLICATE K014280/A1

510(k) NUMBER (IF KNOWN) K014280

DEVICE NAME: LATEX EXAMINATION GLOVES (POWDERED)

INDICATIONS FOR USE:

LATEX EXAMINATION GLOVE (POWDERED) IS A DISPOSABLE DEVICE MADE OF NATURAL LATEX INTENDED FOR MEDICAL PURPOSE THAT IS WORN ON THE EXAMINERS HAND OR FINGER TO PREVENT CONTAMINATION BETWEEN PATIENT AND EXAMINER AND IS POWDERED WITH ABSORBABLE DUSTING POWDER USP CORN STARCH.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014280